The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte L. DAVID WILLIAMS, MICHAEL S. HERSHFIELD, SUSAN J. KELLY, MARK G. P. SAIFER, and MERRY R. SHERMAN

Appeal 2007-1159
Application 09/839,946
Technology Center 1600

Decided: July 18, 2007

Before ERIC GRIMES, LORA M. GREEN, and NANCY J. LINCK, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's Final Rejection of claims 50-53.[1] We have jurisdiction under 35

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[1] Claims 54-59 are also pending, and have been rejected for obviousness-type double-patenting over claims 1-30 of U.S. Patent No. 6,783,965, but that rejection has not been appealed (Br. 5).

U.S.C. § 6(b). Claim 50 is representative of the claims on appeal, and reads as follows:

50. An isolated tetrameric mammalian uricase, wherein at least about 90% of said uricase is in a tetrameric form and less than about 10% of said uricase is in a non-tetrameric aggregated form.

The Examiner relies on the following references:

Conley, "*Purification of Uricase From Mammalian Tissue*," Preparative Biochemistry, Vol. 9, pp. 197-203 (1979).

Conley, "*Thermodynamics and Stoicheiometry of the Binding of Substrate Analogues to Uricase*," Biochem. J., vol. 187, pp. 727-732 (1980).

Lee, "*Generation of cDNA Probes Directed by Amino Acid Sequence: Cloning of Urate Oxidase*," Science, vol. 239, pp. 1288-1290 (1988).

We affirm.

DISCUSSION

Claims 50-53 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lee. As Appellants do not argue the claims separately, claims 51-53 stand or fall with claim 50, and we thus focus our analysis on claim 50.

According to the Examiner:

> Lee [ ] teach[es] the *recombinant* production of full length amino acid sequence of porcine Urate oxidase (also known as uricase) (see abstract lines 8-10) which is tetrameric and is substantially pure. Mammalian uricase is disclosed as a tetramer with subunit size of 32,000 daltons (page 1288, column 2, first paragraph after the abstract). The reference further teaches purification to *homogeneity* of Porcine and murine urate oxidase (see, page 1289, column 2).

(Answer 5 (emphasis in original).)

The Examiner relies on the statements of Lee that in mammals, urate oxidase is present in the liver, "is associated with the peroxisome and exists as a tetramer with an apparent subunit size of 32,000 daltons," (Lee, p. 1288) and that "[p]orcine liver urate oxidase was obtained commercially and purified to homogeneity" (*id.* at 1289) to support the assertion that 100% of the uricase in Lee is in tetrameric form (Answer 9-10).

Appellants argue that the Examiner has taken the above two referenced statements out of context to support the contention that Lee discloses a mammalian uricase that is 100% in the tetrameric form (Reply Br. 3-5). While we agree with Appellants, we still find that Lee anticipates the subject matter of claim 50.

It is axiomatic that in order for a prior art reference to anticipate the claimed invention, it must disclose every limitation of the claimed invention, either explicitly or inherently. *See In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that Lee, when read in light of Appellants' statement of the state of the prior art as set forth in the Specification, anticipates the claimed subject matter of claim 50. Because our reasoning differs from that of the Examiner, and Appellants have not had a fair opportunity to respond to the rejection, we designate our affirmance as a new ground of rejection. *See In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976).

Our mandate is to give claims their broadest reasonable interpretation. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364, 70 USPQ2d 1827, 1830 (Fed. Cir. 2004). "An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed,

as much as possible, during the administrative process." *In re Zletz*, 893 F.2d 319, 322, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Claim 50 uses the term "about" in defining how much uricase must be in tetrameric form in order to be encompassed within the scope of the claim. We first look to the Specification to determine whether Appellants have acted as their own lexicographer in defining "about." *See Merck & Co., v. TEVA Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1369-70, 73 USPQ2d 1641, 1646 (Fed. Cir. 2005). Our review of the Specification, however, does not reveal that "about" has been defined in a way different from its ordinary meaning. We thus interpret "about" consistent with its ordinary meaning. *See id.* "About" may be defined by its ordinary and accepted meaning of "approximately." *See id.*, 395 F.3d at 1372, 73 USPQ2d at 1648. Turning to "approximately," that term may be defined as "nearly exact, not perfectly accurate or correct."[2] We thus interpret the phrase "wherein at least about 90% of said uricase is in a tetrameric form" as encompassing a range of uricase around 90%, and thus any prior art uricase preparation that contains almost 90% of the uricase in tetrameric form is encompassed by claim 50.

Lee teaches that porcine liver urate oxidase was obtained commercially and purified to homogeneity, citing footnote 8 (Lee, p. 1289). Footnote 8 states that porcine liver oxidase was obtained from Sigma, and that murine urate oxidase was purified to homogeneity using the method of Conley (1979). Conley (1979) teaches purification of uricase from

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[2] Dictionary.com. *Dictionary.com Unabridged (v 1.1)*. Random House, Inc. http://dictionary.reference.com/browse/approximately (accessed: June 28, 2007).

mammalian tissue by precipitation under certain dialysis conditions (Conley, abstract).

Appellants assert that the Declaration of Merry R. Sherman, Ph.D, filed under 37 CFR § 1.132 and attached as Exhibit D to the Brief, supports their conclusion that "the authors of Lee would not be expected to have produced an uricase preparation in which at least about 90% of the uricase was in a tetrameric form; instead, more than 10% of the uricase would have been present in a *non-tetrameric* aggregated form." (Br. 12-13 (emphasis in original).) Dr. Sherman at paragraph 5 of the Declaration, referencing the Specification at page 16, lines 5-8, states that "while mammalian uricases *in vivo* (*i.e.*, associated with the peroxisome) exist as a tetramer, isolated purified preparations of natural and recombinant uricase, as indicated in the present specification and as disclosed by Lee, usually contain a mixture of aggregated non-tetrameric forms of the enzyme, in addition to the tetrameric form."

Page 16, lines 5-8 of the Specification, states:

> Purified preparations of naturally occurring and recombinant uricases usually contain a mixture of aggregates of the enzyme, in addition to the tetrameric (140 kDa) form. The percentage of each uricase preparation that is in the tetrameric form generally varies from approximately 20% to 90%.

The Specification, as referenced by the Declaration of Dr. Sherman, thus states that uricase preparations containing up to 90% of uricase in the tetrameric form were known in the prior art. Moreover, as discussed above, claim 50 encompasses uricase preprations containing only approximately 90% of the uricase in tetrameric form. Therefore, claim 50 encompasses

uricase preprations as prepared in the prior art, such as by Lee, and is thus anticipated by the prior art.

CONCLUSION

In summary, we affirm the rejection of claims 50-53 as being anticipated by Lee. Because our reasoning differs from that of the Examiner, we designate the rejection as to those claims as new grounds of rejection.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

37 C.F.R. § 41.50(b)

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